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Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

May 15, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 01 - 59

Sheila Krejci
Administrator
Allina Medical Clinic—Eagan
a.k.a. Oak Point Clinic
1110 Yankee Doodle Road
Eagan, Minnesota 55122

Dear Ms. Krejci:

On April 12, 2001, a representative of the State of Minnesota, acting on behalf of the Food and Drug Administration (FDA), inspected your mammography facility (FDA Certificate #215970). This inspection revealed the following non-compliances involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. Based on the documentation your site presented at the time of the inspection, these non-compliances were documented at your facility:

Repeat Level 2 Non-Compliance:

1. Your facility's policy on mammography complaints is deficient because it lacks a required element. (Each facility shall report unresolved serious complaints to the accreditation body in a manner and timeframe specified by the accreditation body.)

This was also cited during the previous (April 2000) inspection. In a May 26, 2000, letter FDA Radiological Health Specialist Thomas Garvin further advised your site that your policy needed to be revised. The policy was revised to update personnel references but the required element was not added.

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Level 2 Non-Compliance:

2. The time period between previous and current physics surveys for your mammography unit Room #1, unit designation = 1) exceeds 14 months.
3. Failure to produce documents verifying that Radiologic Technologist met the continuing education requirements of having taught or completed at least 15 continuing education units in mammography in 36 months. Note: Until they re-qualify, individuals failing to meet the Continuing Education Requirement must immediately cease performing mammography independently.

FDA acknowledges that based on an April 19, 2001, facsimile to the State of Minnesota Radiation Control Program, Technologist has since re-qualified.

The specific problems noted above appeared on your MQSA Facility Inspection Report which was issued to your facility following the close of the inspection.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within 15 working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures if the findings relate to quality control or other records.

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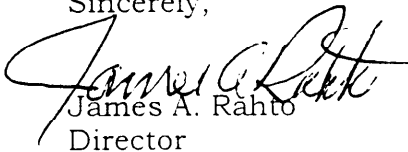
Please submit your response to Thomas W. Garvin, Radiological Health Specialist, Food and Drug Administration, 2675 No. Mayfair Road, Suite 200, Milwaukee, WI 53226-1305.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov/cdrh/mammography/index.html>.

If you have specific questions about mammography facility requirements or about the content of this letter please feel free to phone Mr. Garvin at (414) 771-7167 ext. 12.

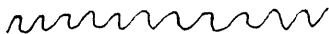
If you have not already done so, please advise your accreditation body (ACR) of your site's name change.

Sincerely,


James A. Rahto
Director
Minneapolis District

TWG/ccl



xc: 
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